In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1722V UNPUBLISHED

ROSE DWORKIS,

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 18, 2022

Special Processing Unit (SPU); Findings of Fact; Onset; Lack of Prior Pain; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Phyllis Widman, Widman Law Firm, LLC, Northfield, NJ, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On November 6, 2019, Rose Dworkis filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on November 7, 2018, or, in the alternative, that the flu vaccine "significantly aggravated a condition." Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

³ Petitioner did not set forth the condition alleged to have been aggravated in her Petition or in any subsequent filing.

For the reasons discussed below, I find that although the medical record establishes that Petitioner had no pre-vaccination history of right shoulder pain, inflammation, or dysfunction that could explain her post-vaccination symptoms, her Table SIRVA claim must be dismissed because the evidentiary record does not support the conclusion that the onset of her pain occurred within 48 hours of vaccination. The claim can therefore only (potentially) proceed as a causation-in-fact claim.

I. Relevant Procedural History

In his April 2, 2021 Rule 4(c) Report, Respondent argued that Petitioner's injury did not meet the definition for a Table SIRVA because she "had a history of gout, inflammatory polyarthropathy, and arthritis prior to her November 7, 2018 flu vaccination." Rule 4(c) Report at 6. ECF No. 32. Respondent also argued that Petitioner has failed to establish that her pain began within 48 hours of vaccination. *Id.* at 6-7. Lastly, Respondent noted that Petitioner neither alleged nor established that her shoulder pain was caused-in-fact by her November 2018 flu shot. *Id.* at 7-8.

In a Scheduling Order filed on April 19, 2021, I expressed the view that based on review of the existing record, a hearing would not be necessary, and that I intended to issue a fact finding as to the onset of Petitioner's injury and whether Petitioner's prevaccination medical history explains her post-vaccination symptoms after providing the parties an opportunity to file briefs and any evidence they wish to have considered. ECF No. 33. Petitioner filed her brief on July 6, 2021, contending that she met her burden of proof for both a Table SIRVA and off-Table claim. ECF No. 35. On August 4, 2021, Respondent filed a response maintaining his position that this case should be dismissed, and that I should issue a finding of fact to that end. ECF No. 36. This matter is now ripe for resolution.

II. Issue

The following issues are contested: whether (1) Petitioner is able to satisfy the first criterion of the Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA claim which requires "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;" and (2) Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination). 42 C.F.R. § 100.3(c)(10)(i)-(ii)(no history of pain requirement; required onset for pain listed in QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition as set forth in Section 11(c)(1). I have discussed the factors to be considered in determining whether a petitioner has met their burden in several recent decisions. I fully adopt and hereby incorporate my prior discussion in section III of the following decisions: *Marrow v. Sec'y of Health & Human Servs.*, No. 17-1964V, 2020 WL 3639775 (Fed. Cl. Spec. Mstr. June 2, 2020); *Robinson v. Sec'y of Health & Human Servs.*, No. 17-1050V, 2020 WL 3729432 (Fed. Cl. Spec. Mstr. June 5, 2020); *Decoursey v. Sec'y of Health & Human Servs.*, No.18-870V, 2020 WL 4673228 (Fed. Cl. Spec. Mstr. July 9, 2020).

In sum, a special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of the petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). Moreover, a special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

IV. Findings of Fact

I have reviewed all of the records filed to date. This ruling, however, is limited to determining (a) whether Petitioner had a pre-vaccination history of pain, inflammation or dysfunction of her right shoulder that explains the shoulder symptoms she experienced after her November 2018 flu shot; and (b) whether the onset of Petitioner's right shoulder pain was within 48 hours of her vaccination. Accordingly, I will only summarize or discuss evidence that directly pertains to these issues.

Petitioner's medical history is significant for allergic rhinitis (beginning on June 24, 2013), acute pharyngitis (beginning on June 10, 2013), chronic hyperglycemia and chronic vitamin D deficiency. See Ex. 3 at 2. Petitioner's medical records do not include any additional information concerning these conditions, including Petitioner's symptoms or treatment history.

- Petitioner's medical history is also significant for uterovaginal prolapse, mild diverticulosis, herpes zoster, postherpetic neuralgia ("PHN"), and hypertension. See Ex. 3 at 2, 5, 7, 9, 11; Ex. 4 at 2-3, 4, 14, 16-17, 19, 22, 25, 26, 28.
- Petitioner's medical records indicate that she was diagnosed with idiopathic gout and inflammatory polyarthropathy in September 2014. See Ex. 3 at 2. Petitioner's medical records do not include any additional information concerning these conditions, including Petitioner's symptoms or treatment history.
- In her supplemental affidavit, signed on March 23, 2021, Petitioner avers that she
 presented to the Bergen Kidney Center on September 11, 2014 due to left elbow
 inflammation and tenderness. Ex. 9 at 1. Petitioner states that this condition was
 determined to be gout and that "the inflammation was a one-time episode of short
 duration and no further treatment was required." Id.
- It was noted on a medical summary sheet that on November 12, 2015, Petitioner's left elbow was described as hot, red, and tender. Ex. 3 at 2. She was noted to be taking Aldactazide. *Id*.
- Petitioner presented to Dr. Ivan A. Friedrich, her primary care physician, on August 2, 2018. Ex. 4 at 4. The medical note documenting this visit indicates that Petitioner complained of arthritis, but denied back pain, gout, joint deformity, joint pain, muscle weakness and stiffness. *Id.* at 5.
- An August 22, 2018 medical note indicates that Petitioner's "[p]ertinent positive symptoms include arthritis." Ex. 4 at 26. Petitioner again denied back pain, gout, joint deformity, joint pain, muscle weakness and stiffness. *Id.* at 27.
- On November 7 2018, Petitioner presented to Dr. Friedrich for follow up of her PHN. Ex. 4 at 14-16. The medical note documenting this visit indicates that Petitioner complained of numbness and tingling. *Id.* at 14. During this visit, Petitioner was administered a flu shot in her right shoulder. *Id.* at 14; Ex. 1.
- In her affidavit, signed on June 24, 2019, Petitioner avers that "[w]ithin a few hours of receiving the vaccine, I felt soreness and pain at the injection site as well as in my upper arm. At the time I thought it was a normal reaction to the vaccine." Ex. 2 at 1.
- Petitioner presented to Dr. Friedrich on January 16, 2019 (ten weeks post vaccination) regarding PHN. Ex. 4 at 11-13. Although Dr. Friedrich later indicated

- that Petitioner complained about shoulder pain on this date (see Ex. 8 at 1), the contemporaneous medical record does not document any such statement. *Id.*
- In her affidavit, Petitioner also states that she reported arm and shoulder pain during her January 16, 2019 appointment with Dr. Friedrich. Ex. at 2 at 1. Petitioner further indicates that although he instructed her to wait two months before following up, on February 19, 2019, she asked him to refer her to an orthopedist. *Id*.
- Petitioner presented to Dr. Michael Pizzillo at Englewood Orthopedic Associates on March 6, 2019 with "a 3-month history of right shoulder pain." Ex. 6 at 56. The medical note indicates that Petitioner reported "insidious onset in November 2018." *Id.* She was assessed with impingement syndrome of the right shoulder and right shoulder trapezius parascapular muscle spasm. *Id.* Formal physical therapy was recommended. *Id.*
- On March 12, 2019, Petitioner reported "pain in right arm/shoulder over the past [four] months" to her physical therapist. Ex. 6 at 54. The note documenting this visit indicates that Petitioner's symptoms "may be related to a flu injection [four] months ago." *Id*.
- A May 3, 2019 physical therapy note indicates that Petitioner reported "pain in right upper arm/shoulder over the past 6 months." Ex. 6 at 28. It was further indicated that Petitioner's symptoms were "possibly related to a flu injection around that time." Id.
- On May 7, 2019, Petitioner presented to Dr. Pizzillo regarding a continuation of right shoulder issues. Ex. 6 at 26-27. On exam, Petitioner's right shoulder was tender over the trapezius and the parascapular musculature, and her active range of motion was "painful at the extremes of forward flexion and abduction."
- Petitioner attended 30 sessions of physical therapy from March 12, 2019, through July 9, 2019. Ex. 6 at 63-64. The final physical therapy note indicates that her right arm and shoulder symptoms were possibly related to a flu vaccination. *Id.* at 63.
- Petitioner presented to Dr. Pizzillo on July 11, 2019. Ex. 6 at 61. She reported "minimal complaints of pain with the exception of certain movements." *Id.* Petitioner's right shoulder exam revealed "near full and symmetric" range of motion, a positive impingement sign, and good motor strength. *Id.*
- Petitioner again presented to Dr. Friedrich on January 6, 2020. Ex. 7 at 2-5. Her complaints included arthritis. *Id.* at 3.

A. Pre-Vaccination History

Respondent correctly asserts that Petitioner's medical records reflect a prevaccination history of gout, inflammatory polyarthropathy, and arthritis. However, Respondent has not argued - and the medical records do not reflect - that these conditions are connected to or explain Petitioner's post-vaccination symptoms.

Petitioner acknowledges that she was diagnosed with gout in 2014. Brief at 2-3. However, in addition to arguing that "the inflammation was a one-time episode" that occurred three years prior to vaccination, she also notes that her symptoms were limited to her *left* elbow. *Id.* This assertion is corroborated by a medical record indicating that Petitioner's left elbow was hot, red, and tender in November 2015, and there is no indication that these symptoms extended to her vaccinated/right arm or shoulder. See Ex. 3 at 2.

Petitioner's medical records offer no information concerning her 2014 inflammatory polyarthropathy diagnosis, including its duration or symptoms. And while there is some evidence that Petitioner generally complained about her arthritis, the medical records do not reveal any specific information about its effect and there is no indication that this condition had an impact on her right shoulder or arm. Therefore, I find that, on this record, nothing in Petitioner's pre-vaccination history would explain her post-vaccination symptoms.

B. Onset

This case presents several issues regarding Petitioner's success in establishing onset consistent with the Table's 48 hour requirement. First, there is an uncontroverted ten-week gap from vaccination to Petitioner's first documented report of shoulder pain, which undermines somewhat Petitioner's onset contentions. While some delay in seeking treatment is relatively common in SIRVA cases, I have previously noted that "[i]t is reasonable to expect the average Program claimant might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain." *Pitts v. Sec'y of Health & Human Servs.*, 18-1512V, 2020 WL 2959421, at *5 (Fed. Cl. Spec. Mstr. April 29, 2020).

This gap is compounded by the fact that Petitioner had an intervening medical visit between her November 2018 flu shot and this first documented report of right shoulder pain. Although Petitioner avers that she shared these issues seven weeks earlier, during her January 16, 2019 appointment with Dr. Friedrich, the contemporaneously created medical record is silent on the matter.

Petitioner has attempted to remedy this omission by submitting an August 11, 2020 medical record (authored by Dr. Friedrich) that clarifies what was spoken about at the

January 2019 appointment. However, this record makes no mention of *when* Petitioner's shoulder pain started. And while such after-the-fact statements can be deemed persuasive (especially to the extent they do not contradict prior record statements), they inherently are somewhat less probative than contemporaneous evidence. The fact that the revising/amending statement about what was discussed was added and obtained after the litigation had commenced is also unhelpful (although it does not necessarily mean the subsequent statement is false).

Moreover, many record onset references are quite vague. For example, although Petitioner maintains that the onset of her pain occurred "within a few hours" of vaccination, on March 6, 2019, she reported "insidious onset in November 2018." Ex. 6 at 56 (emphasis added). This generalized reference to the start of shoulder pain is also reflected in a March 12, 2019 physical therapy record, noting that Petitioner's four-month history of right arm and shoulder pain "may be related to a flu injection four months ago." Id. at 54. See also Ex. 6 at 28 (May 3, 2019 physical therapy note documenting Petitioner's report of "pain in right upper arm/shoulder over the past 6 months . . . possibly related to a flu injection around the same time"); Id. at 63 (July 9, 2019 physical therapy note documenting Petitioner's report of an eight-month history of right-sided pain that is "possibly related to a flu injection around that time."). While such language certainly supports a finding that Petitioner suffered right-sided shoulder pain around the time she received the flu shot, it does not support a finding that she more likely than not suffered onset of her condition within 48 hours of her vaccination.

I acknowledge that the standard applied to resolving onset for an alleged SIRVA is liberal and will often permit a determination in a petitioner's favor, especially in the absence of fairly contemporaneous and direct statements within the petitioner's medical records to the contrary. However, not every case can be so preponderantly established. Ultimately, the resolution of such fact issues involves weighing different items of evidence against the overall record.

Therefore, after considering the record as a whole, I find there is not preponderant evidence to establish that Petitioner suffered the onset of symptoms within 48 hours of her flu vaccination as required by the Vaccine Injury Table. 42 C.F.R. § 100.(3)(a)(I)(C).

Although Petitioner asserted in her brief that, alternatively, her injury was caused-in-fact by the November 2018 flu vaccination, she has to date failed to provide any support for this claim. However, the record *does* support onset having occurred shortly after vaccination and, seemingly, all other criteria for a Table SIRVA claim appear satisfied. Therefore, Petitioner very likely has a viable non-SIRVA claim. To that end, I urge the

7

_

⁴ This record also indicates that Petitioner reported a three-month history of shoulder pain - which would date back to December 6, 2018. However, given that Petitioner specifically reported a November 2018 onset, it appears that this is simply an error in calculation.

parties to make one final brief attempt at settlement – as I would anticipate that even after transfer, Petitioner's claim could prove meritorious despite her inability to meet one Table element.

V. Scheduling Order

Petitioner has not preponderantly established that the onset of her pain occurred within 48 hours of vaccination. Accordingly, the Table SIRVA claim is DISMISSED, although Petitioner may pursue the claim as a non-Table, causation-in-fact claim. The parties shall file a status report on or before **Wednesday**, **August 17**, **2022**, regarding their settlement efforts. The matter shall be transferred thereafter if the parties do not report significant progress in reaching an agreement at that time.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master